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H. R. 1165

To amend the Federal Food, Drug, and Cosmetic Act to establish additional authorities to ensure the safe and effective use of drugs, to establish whistleblower protections for certain individuals, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 16, 2007

Mr. MARKEY introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish additional authorities to ensure the safe and effective use of drugs, to establish whistleblower protections for certain individuals, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Swift Approval, Full Evaluation Drug Act'' or the ''SAFE Drug Act''.

SEC. 2. POSTMARKET STUDIES REGARDING DRUG SAFETY; POSTMARKET LABELING CHANGES.

(a) POSTMARKET ORDERS REGARDING STUDIES.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following section:

"SEC. 505C. POSTMARKET STUDIES REGARDING DRUG SAFETY.

"(a) POSTMARKET ORDERS.—Within 30 days after receiving evidence of a significant issue regarding the safety or lack of effectiveness of an approved drug, including reports of adverse events, studies conducted or reports released by the Food and Drug Administration, the National Institutes of Health, the Agency for Healthcare Research and Quality, or another relevant agency, actions or reports by regulatory agencies in foreign countries, or studies or case reports published in scientific or academic journals, the Secretary, after providing public notice of the significant safety or effectiveness issue, may order the holder of the approved application to conduct a study or studies to address the issues involved. Each such notice and order shall be published in the Federal Register.

"(b) RESTRICTIONS ON USE.—

"(1) IN GENERAL.—An order under subsection (a) with respect to an approved drug may, during the period in which the study involved is conducted,

establish restrictions on the distribution or use of the drug if the Secretary determines that such restrictions are necessary to ensure the safe and effective use of the drug during such period.

''(2) CERTAIN AUTHORITIES.—Restrictions that may be established by the Secretary under paragraph (1) with respect to a drug include the following:

''(A) Restricting distribution to certain facilities or physicians with special training or experience.

''(B) Conditioning distribution on the performance of specified medical procedures.

''(C) Restricting direct-to-consumer advertisements for the drug.

''(3) TERMINATION.—The Secretary may, on the basis of the results of a study ordered pursuant to subsection (a) or other evidence, continue the restrictions under paragraph (1), terminate restrictions established, or establish different restrictions, as necessary to ensure the safe use of the drug. The Secretary shall notify the sponsor of the decision to extend, terminate, or change the restrictions no later than 30 days after the date on which the results of the study involved are submitted to the Secretary.

''(c) DEFINITION.—For purposes of this section, the term 'approved drug' means a drug for which an approved application under section 505 is in effect or for which a biologics license under section 351 of the Public Health Service Act is in effect.''.

(b) NEW DRUG APPLICATIONS; POSTMARKET STUDIES PURSUANT TO ACCELERATED APPROVAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following subsection:

''(o)(1) The Secretary shall amend subpart H of part 314 of title 21, Code of Federal Regulations, to establish the following policies:

''(A) As a condition of the approval under such subpart of a new drug on or after the date of the enactment of the SAFE Drug Act, the Secretary shall require that one or more postmarket studies of the drug be conducted.

''(B) The Secretary may not approve the application involved unless—

''(i) the sponsor has submitted to the Secretary the protocols for each such study;

''(ii) the Secretary has approved the protocols; and

''(iii) the Secretary and the sponsor have agreed on a timeframe, including designated milestones, for the prompt completion of the study, which timeframe assumes due diligence by the sponsor in conducting the study.

''(C) The Secretary shall require that, after the application is approved under such subpart and the drug enters commercial distribution, the drug be marketed in accordance with the following:

''(i) The distribution and use of the drug shall be restricted in accordance with such subpart.

''(ii) Until the Secretary determines that the sponsor has fulfilled its commitments under subparagraphs (A) and (B), the labeling of the drug shall bear—

''(I) a statement that the Food and Drug Administration is requiring a study or studies to confirm the safety and effectiveness of the drug; and

''(II) a statement providing a clear and concise summary of the outstanding issues or questions to be addressed in such required studies.

''(iii) Until the Secretary determines that the sponsor has fulfilled its commitments under subparagraphs (A) and (B), the labeling of the drug shall bear a statement providing as follows: 'This product received conditional approval from the FDA under its accelerated approval process. It will not receive full approval until completion of further testing to confirm safety and/or efficacy. For further information please contact your physician.'.

''(iv) Direct-to-consumer advertisements for the drug shall be restricted until—

''(I) the Secretary determines that the sponsor has fulfilled its commitments under subparagraphs (A) and (B); and

''(II) the drug has been approved under such part 314 independently of subpart H of such part.

''(2) The Secretary shall amend part 314 of title 21, Code of Federal Regulations, to establish the following policies regarding postmarket studies that, on or after the date of the enactment of the SAFE Drug Act, are required pursuant to approval of a new drug under subpart H of such part or under section 506(b)(2) of this Act:

''(A) If a required study is not completed by two years after the date on which the new drug was so approved, the Secretary shall, promptly after the expiration of such period, convene a public meeting of the appropriate advisory committee to review the progress of the study. Such review shall include the assessment of compliance with the timeframe for prompt completion of the study as agreed to by the company and the Secretary under paragraph (1)(B)(iii) or under section 506(b)(2) (as the case may be), the quality of study conduct, rates of enrollment overall and by institution, the barriers to progress, and whether the sponsor is acting with due diligence. At the meeting, the advisory committee shall determine whether it is in the best interest of the public to allow the sponsor to continue marketing the drug until the study is completed or whether it is in the best interest of the public to suspend the commercial marketing of the drug until the study is completed.

''(B) If the drug was approved on the basis of animal efficacy data because human efficacy studies are not ethical or feasible, the holder of the approved application shall conduct studies when ethical

and feasible to verify and describe clinical benefit and to assess the product's safety and effectiveness.

''(C) If the results of a completed study that was so required are inconclusive or the risk-to-benefit profile cannot be positively established, the Secretary shall withdraw the product for commercial distribution. If a required study is not completed by five years after the date of approval, the results of the study are presumed to be inconclusive. The product may only be made available to a patient who—

''(i) according to a health care professional has previously benefitted from the product; and

''(ii) has signed a statement of informed consent that—

''(I) states that the patient has received notice from the sponsor that the results of completed studies on the product have proven to be inconclusive or the risk-to-benefit profile cannot be positively established; and

''(II) identifies the risks of continuing the product.

Otherwise the product shall be unavailable except in a research setting until the product can meet the

same standard of safety and effectiveness that exists for full approval.''.

(c) ENFORCEMENT REGARDING POSTMARKET STUDIES.—

(1) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(y) If it is a drug with respect to which there is a failure to comply with a requirement under section 505(o)(1), an order under section 505C, or a requirement under section 506(b)(2).''.

(2) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(g)(1)(A) Any person who violates section 301(a), 301(b), or 301(c) by reason of section 502(y) shall be subject to a civil penalty of not more than 100 percent of the gross profits received by the sponsor from sales of the drug, or $1,000,000, whichever is greater, subject to subparagraph (B).

''(B) If any harm to a consumer occurs as a result of a violation referred to in subparagraph (A), the person involved may be subject to a civil penalty of not more than an amount equal to 300 percent of the gross profits received by the person, or $3,000,000, whichever is greater.

''(2) Any person who fails to act with due diligence to complete a postmarket study required under section 506(b)(2), or under subpart H of part 314 of title 21, Code of Federal Regulations, shall be subject to a civil penalty of not more than the amount that applies under subparagraph (A) or subparagraph (B) of paragraph (1) (as the case may be) for a violation referred to in such paragraph. The Secretary shall by regulation define the term 'due diligence' for purposes of this paragraph.

''(3) The provisions of paragraphs (3) through (5) of subsection (f) apply to a civil penalty under subparagraph (A) or (B) of paragraph (1) or under paragraph (2) to the same extent and in the same manner as such provisions apply to a civil penalty under paragraph (1) or (2) of such subsection.''.

(d) POSTMARKET LABELING CHANGES.—Section 502 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (c)(1) of this section, is amended by adding at the end the following:

''(z) If it is a drug and the manufacturer of the drug or product fails to make changes to a product's labeling in compliance with an order of the Secretary, issued on the basis of clinical evidence (including studies submitted to the Secretary, an analysis of adverse events reports, studies conducted or

reports released by the Food and Drug Administration, the National Institutes of Health, the Agency for Healthcare Research and Quality, or another relevant agency, actions or reports by regulatory agencies in foreign countries, or studies published in scientific or academic journals), that the labeling of the drug be modified to include specific wording required by the Secretary to ensure the safe and effective use of the drug.''.

(e) RULE OF CONSTRUCTION REGARDING CERTAIN PEDIATRIC STUDIES.—The amendments made by this section establish authorities in addition to, and not in lieu of—

(1) the program under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a); and

(2) authorities under section 505B of such Act (21 U.S.C. 355b).

SEC. 3. WHISTLEBLOWER PROTECTIONS.

(a) PROHIBITION.—It shall be unlawful for any person to discharge, demote, suspend, reprimand, investigate, or take or fail to take any other personnel action that in any manner discriminates against any covered individual, or in any other manner discriminate against any covered individual (including by a denial, suspension, or revocation

of a security clearance or by any other security access determination, or by denial of award of a Federal contract or subcontract), or to threaten or recommend the discharge, demotion, suspension, reprimand, investigation, other personnel action (or rejection of such action) that in any manner discriminates against any covered individual, or other manner of discrimination if such action, discrimination, or recommendation is due, in whole or in part, to any lawful act done, perceived to have been done, or intended to be done by the covered individual—

(1) to provide information, cause information to be provided, or otherwise assist in an investigation or proceeding regarding any conduct which the covered individual reasonably believes constitutes evidence of a violation of any law, rule, or regulation, a substantial and specific threat to public health or safety, an abuse of authority, fraud, waste, or mismanagement of public funds, censorship, distortion, or suppression of scientific information, research, or analysis, or the willful disclosure of false, misleading, or incomplete scientific information, if the information or assistance is provided to or the investigation or proceeding is conducted by—

(A) a Federal, State, or local regulatory or law enforcement agency (including an office of

Inspector General under the Inspector General Act of 1978);

(B) any Member of Congress, any committee of Congress, or the Government Accountability Office;

(C) any person with supervisory or managerial authority over the covered individual (or any other person who has the authority to investigate, discover, or terminate misconduct); or

(D) a potential witness to or other person affected by or aware of the conduct described in this section who has the authority to investigate, discover, or terminate misconduct;

(2) to file, cause to be filed, testify, participate in, or otherwise assist in a proceeding or action filed or about to be filed relating to an alleged violation of any law, rule, or regulation; or

(3) to refuse to violate or assist in the violation of any law, rule, or regulation.

(b) ENFORCEMENT ACTION.—

(1) IN GENERAL.—A covered individual who alleges discharge or other discrimination by any person in violation of subsection (a) may seek relief under paragraph (3) by—

(A) filing a complaint with the Secretary of Labor; or

(B) if the Secretary has not issued a final decision within 180 days after the filing of the complaint and there is no showing that such delay is due to the bad faith of the claimant, bringing an action at law or equity for de novo review in the appropriate district court of the United States, which shall have jurisdiction over such an action without regard to the amount in controversy.

(2) PROCEDURE.—

(A) IN GENERAL.—An action under paragraph (1)(A) shall be governed under the rules and procedures set forth in section 42121(b) of title 49, United States Code.

(B) EXCEPTION.—Notification made under section 42121(b)(1) of title 49, United States Code, shall be made—

(i) to the person named in the complaint; and

(ii) to the person's employer.

(C) BURDENS OF PROOF.—An action brought under paragraph (1)(B) shall be governed by the legal burdens of proof set forth in

section 42121(b) of title 49, United States Code.

(D) STATUTE OF LIMITATIONS.—An action under paragraph (1) shall be commenced not later than 6 years after the date on which the violation occurs.

(3) REMEDIES.—

(A) IN GENERAL.—A covered individual prevailing in any action under this subsection shall be entitled to all relief appropriate to make the covered individual whole.

(B) DAMAGES.—Relief for any action under this subsection shall include—

(i) reinstatement with the same seniority status and employment grade or pay level (or the equivalent) that the covered individual would have had, but for the discrimination;

(ii) compensatory damages, including the amount of any back pay, with interest;

(iii) compensation for any special damages sustained as a result of the discrimination, including litigation costs, expert witness fees, and reasonable attorney fees; and

(iv) punitive damages in an amount not to exceed the greater of 3 times the amount of any monetary damages awarded under this section (apart from this paragraph) or $5,000,000.

(c) CRIMINAL PENALTIES.—

(1) IN GENERAL.—Any person who violates subsection (a) shall be fined under title 18 of the United States Code, imprisoned not more than 10 years, or both.

(2) REPORTING REQUIREMENTS.—The Attorney General of the United States shall (based on such periodic reports and other information from the Department of Labor as the Attorney General may require) submit to the Congress an annual report on the enforcement of paragraph (1). Each such report shall—

(A) identify each case in which formal charges under paragraph (1) were brought;

(B) describe the status or disposition of each such case; and

(C) in any action under subsection (b) in which the covered individual was the prevailing party or the substantially prevailing party, indicate whether or not any formal charges under

paragraph (1) have been brought and, if not, the reasons therefor.

(d) RIGHTS RETAINED BY COVERED INDIVIDUAL.—Nothing in this section shall be deemed to diminish the rights, privileges, or remedies of any covered individual under any Federal or State law, or under any collective bargaining agreement. The rights and remedies in this section may not be waived by any agreement, policy, form, or condition of employment.

(e) NOTIFICATION.—The provisions of this section shall be prominently posted in any place of employment to which this section applies.

(f) DEFINITIONS.—For purposes of this section:

(1) The term ''covered individual'' means an employee or a contractor or subcontractor of the Food and Drug Administration.

(2) The term ''lawful'' means not specifically prohibited by law.

SEC. 4. RIGHT TO PUBLISH.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following section:

''SEC. 565. RIGHT TO PUBLISH.

''Officers and employees of the Food and Drug Administration, and individuals sponsored by such Adminis-

tration, may publish in peer-reviewed journals and other scientific publications, and make oral presentations at professional society meetings and other meetings of their peers, unless publication or presentation of the data is subject to Federal export control or national security laws or regulations, or is proprietary information. The right to publish or present such data cannot be waived by any agreement, policy, form, or condition of employment.''.

SEC. 5. PROVIDING FDA ADVISORY COMMITTEES WITH COMPLETE INFORMATION.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 4 of this Act, is amended by adding at the end the following section:

''SEC. 566. PROVIDING ADVISORY COMMITTEES WITH COMPLETE INFORMATION.

''(a) IN GENERAL.—In conjunction with any hearing of an advisory committee of the Food and Drug Administration, the Secretary shall, at the request of any officer or employee of the Administration whose employment duties relate to the topic of the hearing, allow the officer or employee a reasonable amount of time to present to the advisory committee information on such topic.

''(b) TIMING OF PRESENTATION.—An advisory committee shall provide a period of time to an officer or employee for a presentation under subsection (a) that is sepa-

rate from the period of time allotted to the public for the hearing involved.''.

SEC. 6. PRESERVING SCIENTIFIC INTEGRITY.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 5 of this Act, is amended by adding at the end the following section:

''SEC. 567. PRESERVING SCIENTIFIC INTEGRITY.

''(a) PROHIBITION.—An officer or employee of the Food and Drug Administration shall not direct any other officer or employee of the Administration—

''(1) to censor, distort, or suppress any scientific research, analysis, opinion, or recommendation; or

''(2) to willfully disclose scientific information that is false, misleading, or incomplete.

''(b) APPROPRIATE DISCIPLINARY ACTION.—The Secretary shall subject any officer or employee who violates subsection (a) to appropriate disciplinary action (which may include dismissal).

''(c) REPORTING BY IG.—Not less than 1 year after the date of the enactment of this section, and annually thereafter, the Inspector General of the Department of Health and Human Services shall submit a report to the Congress—

''(1) identifying each disciplinary action under subsection (b) during the preceding 12 months; and

''(2) describing the circumstances of each such disciplinary action.''.

SEC. 7. TRANSPARENCY OF APPROVAL DECISIONS.

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 2(b) of this Act, is further amended by adding at the end the following:

''(p) TRANSPARENCY OF APPROVAL DECISIONS.—

''(1) SUMMARY STATEMENT.—Not later than 48 hours after the approval of an application filed under subsection (b) or (j), the Secretary shall publish a summary statement of the scientific basis for such approval and how the final decision balanced the risks and benefits.

''(2) CONTENTS.—A summary statement under paragraph (1) shall be dated and shall include the following:

''(A) A summary of the factual, scientific, and related issues considered during the approval process, including—

''(i) an explanation of the risks and the benefits of the drug involved; and

''(ii) the scientific rationale for the final decision.

''(B) Identification by name of each officer or employee of the Food and Drug Administration who participated in the decision to approve the application.

''(C) A description of—

''(i) any significant controversy or difference of opinion between two or more officers or employees described in subparagraph (B) relating to the decision to approve the application; and

''(ii) the resolution of each such controversy or difference of opinion.

''(3) DISSENTING AND OTHER VIEWS.—Any officer or employee of the Food and Drug Administration who participates in the decision to approve an application filed under subsection (b) or (j) may submit a statement of views on the matter for inclusion in the applicable summary statement. Upon receipt of such a statement of views, the Secretary shall attach the statement of views, without alteration, as an addendum to the summary statement.

''(4) SUBSEQUENT CHANGES.—After publication of a summary statement under this subsection, the Secretary—

''(A) shall not alter the text of the summary statement; and

''(B) may prepare a description of changes to the summary statement in a separate document and attach the document as an addendum to the summary statement.

''(5) CONFIDENTIAL INFORMATION.—This subsection does not authorize the disclosure of any trade secret or privileged or confidential commercial or financial information described in section 552(b)(4) of title 5, United States Code, unless the Secretary determines that such disclosure is necessary to protect the public health.''.

SEC. 8. BIENNIAL REPORTS ON APPROVED APPLICATIONS SUPPORTED BY NON-INFERIORITY STUDIES.

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 7 of this Act, is amended by adding at the end the following subsection:

''(q) BIENNIAL REPORTS ON APPROVED APPLICATIONS SUPPORTED BY NON-INFERIORITY STUDIES.—The Secretary shall submit to the Congress biennial reports on approved applications under subsection (b) (including supplemental applications) that have been supported by data from one or more non-inferiority studies. For each such

application, the report shall include the following information:

''(1) The name of the drug listed in application.

''(2) The name of the sponsor.

''(3) The date of the approval.

''(4) The name of each drug used as an active control in the non-inferiority studies used to support the application.

''(5) The indication studied.

''(6) The primary and secondary endpoints of the non-inferiority studies.

''(7) The margins used in such studies.

''(8) The explanation required by section 314.l26(b)(2)(iv) of title 21, Code of Federal Regulations, as to why the drugs should be considered effective in the study.''.

SEC. 9. BIANNUAL REPORTS REGARDING POSTMARKET STUDIES.

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 8 of this Act, is amended by adding at the end the following subsection:

''(r) BIANNUAL REPORTS REGARDING POSTMARKET STUDIES.—The Secretary shall submit to the Congress biannual reports that provide the following information:

''(1) The number of enforcement actions taken to ensure that sponsors are complying with the requirements to complete postmarketing studies under subsection (o) and sections 505C and 506(b)(2), together with a description of each such action.

''(2) The measures taken by the Secretary to establish a system to ensure effective monitoring of the status of all such postmarketing studies, together with a description of the status of that system.

''(3) The measures taken by the Secretary to develop a system to track information about ongoing postmarketing safety issues, together with a description of the status of that system.''.

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